AL/AO-TR-1996-0157

UNITED STATES AIR FORCE
ARMSTRONG LABORATORY

PERFORMANCE ASSESSMENT OF THE BIRD PRODUCTS, CORP BIRD AVIAN PORTABLE VENTILATOR (MILITARY VERSION) MODEL 15300 IN THE HYPERBARIC ENVIRONMENT

Eugene J. Wall
William G. Jackson, Jr.

AEROSPACE MEDICINE DIRECTORATE
HYPERBARIC MEDICINE DIVISION
2509 Kennedy Circle, Suite 309
Brooks Air Force Base, TX 78235-5304

February 1997

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EUGENE J. WALL, Captain, USAF,NC
Project Scientist

E. GEORGE WOLF, JR., Colonel, USAF, MC, CFS
Chief, Hyperbaric Medicine Division

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY (Leave blank)

2. REPORT DATE
February 1997

3. REPORT TYPE AND DATES COVERED

4. TITLE AND SUBTITLE
Performance Assessment of the Bird Products, Corp Bird Avian Portable Ventilator (Military Version) Model 15300 in the Hyperbaric Environment

5. FUNDING NUMBERS

6. AUTHOR(S)
Eugene J. Wall
William G. Jackson, Jr.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Armstrong Laboratory (AFMC)
Aerospace Medicine Directorate
Hyberbaric Medicine Division
2509 Kennedy Circle
Brooks AFB TX 78235-5304

8. PERFORMING ORGANIZATION REPORT NUMBER
AL/AO-TR-1996-0157

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution is unlimited.

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 words)

The Bird Avian Ventilator (BAV), presently used by the USAF Emergency Medical Services as a transport ventilator, has recently been accepted for use on cargo aircraft for USAF aeromedical evacuation. The BAV was tested in the "control" mode of operation at 1ATA, 2 ATA, 2.36 ATA and 3 ATA. An artificial lung simulator was set for testing two lung compliances: 0.10 L/cm H_2O and 0.05 L/cm H_2O. Required settings for using the BAV in the control mode were: tidal volume (TV,ml), flow (l/min), and breath rate (bpm). Measured tidal volumes (TV_m) were recorded at three depths and ten tidal volume settings (TV_s = 200 to 2000, by 200ml increments) using a 1:2 inspiratory/expiratory test breath cycle ratio. Three independent measures of proximal airway pressure were determined from identical sites on the patient breathing circuit. Positive end expiratory pressure (PEEP) was not used in this test. The model fitting the data most satisfactorily was $TV_m = TV_s \times [\ \alpha\ (\alpha + \text{ATA} - 1)]^{\beta}$. A nonlinear least squares program (SAS NLIN) was used to obtain estimates of α (0.880) and β (0.554). Estimates of flows were computed as 3 x (Rate) x TV, since I + E = 1 + 2 = 3. Results show structural integrity of the BAV was unaffected by increased ambient pressures, and no aberrant functioning was observed when compared to 1 ATA baseline performance checks. Initially, however, the membrane control switches became inoperative under increased atmospheric pressure and required venting. With the BAV in control mode during volume cycled ventilation, our findings show this ventilator can provide safe and acceptable tidal volumes, in conjunction with proximal airway pressures and breath rate when exposed to hyperbaric pressures. In conclusions, a conversion table was developed to assist users in selecting corrected settings on the ventilator at the tested pressures listed above.

14. SUBJECT TERMS
Aeromedical evacuation
Bird Avian Ventilator (BAV)
Transport ventilator

15. NUMBER OF PAGES
20

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	UL

NSN 7540-01-280-5500

Standard Form 298 (Rev.2-89)
Prescribed by ANSI Std. Z39-18
298-102

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INTRODUCTION

The Oxford Penlon has been the ventilator of choice for the Davis Hyperbaric Laboratory for many years. Blanch, et al., in 1991 found that of 19 ventilators evaluated, the Oxford Penlon was the ventilator of choice for the multiplace hyperbaric chamber.**(4)**. Although this unit is limited in operational capability, and is expensive to repair, the Oxford Penlon ventilator has proven reliable.

Technology continues to **(1)** evolve and new ventilator systems are being developed. The Bird Avian portable ventilator (BAV) has undergone testing by the United States Air Force (USAF) for aeromedical evacuation and is presently used as a transport ventilator by paramedic services at Wilford Hall Medical Center, USAF Medical Treatment Facility. The (BAV) was tested by the Davis Hyperbaric Laboratory, Brooks AFB TX.

Test Objectives

The overall objective was to evaluate the performance of the BAV in the hyperbaric environment. Specific objectives focused on the:

1. Structural integrity of the ventilator during and after exposure to increased atmospheric pressure.

2. Measurement of clinical variables for safe, acceptable limits (breath rate, tidal volume, flow rate, and proximal airway pressure) at 1 atmosphere absolute (ATA), 2 ATA, 2.36 ATA, and 3 ATA, on lung compliances of .10 L/cm H2O and .05 L/cm H2O respectively **(5)**, **(6)**. (No evaluation of the influence of pressure on the electronic components was performed)

METHODS & MATERIALS

Test Item Description

The BAV (model 15300) is a portable, electronically controlled, time or volume-cycled, pressure-limited ventilator. It is controlled by a microprocessor that continuously monitors patient airway pressure, control settings, alarms and power signals.

It can support a variety of ventilation modes such as control, assist control and synchronized intermittent mandatory ventilation. The BAV provides the operator with various alarms including automatic apnea backup ventilation, 0-100 liter per minute (lpm) peak flow, 0-150 breath per minute (bpm), 10-100 cmH_20 peak inspiratory pressure, proximal airway pressure monitoring, and audio/visual alarms for high/low peak pressures, apnea, inverse inspiratory/ expiratory (I:E) ratio, and patient circuit disconnect. The BAV uses an internal, rechargeable battery, 115-230 VAC, 50-400 HZ multivoltage switch selectable AC power supply and 12 VDC power cable to allow for connection to external 11-30 VDC positive or negative ground power sources. The battery pack may be recharged within the range of either of the aforementioned AC or DC voltages.

The BAV operates from gas sources capable of delivering 40-60 pounds per square inch, gauge PSIG. These include compressed gas cylinders (air, oxygen, or air/oxygen mixtures), medical grade air compressors, Patient Therapeutic Liquid Oxygen (PT LOX) or on-board aircraft sources. The dimensions of the BAV are as follows: Size: 12 inches (305 mm) wide x 10 inches (254 mm) high x 5 inches (127mm) deep. Weight: Control module less than 10 lb (4.45 kg) including battery; multivoltage AC power supply 1.75 lb.(0.9kg). The BAV comes in a carrying case with the following components: external multivoltage AC power supply, 12 VDC power cables (one with cigarette lighter plug, one with undetermined end {no plug}), reusable patient exhalation valve, 6ft. of oxygen source supply hose (green), 6 ft. of air source supply hose (yellow), reusable positive end expiratory pressure (PEEP) valve, 6 ft. of 15 mm patient gas source supply hose, two 6 ft. lengths of 3.2 mm tubing, and one commercial operating instruction manual **(2)**.

Figure 1. Bird Avian Portable Ventilator, Model 15300

Military Version Differences

The Bird Avian portable ventilator, military version has some unique differences from the commercial (off the shelf) version. The differences are as follows:

1. Pop off valve is rated at 39.4inH20 (100 cmH20) pressure on both the military and commercial versions; however, on the military version this valve is locked and is not adjustable.

2. Manual breath button provides a continuous flow of gas for as long as it is depressed.

3. Anti- suffocation valve, located within in the patient breathing circuit, is standard.

Test Equipment

1. Bird Avian Ventilator (military version)
2. Biotek VT2 ventilator analyzer
3. Ohmeda 5410 volume monitor
4. Carrier Demodulator Strip Chart
5. Biotek Universal Biometer (DPM-III)
6. Validyne DP-15 Transducer (Diaphragm of 32)
7. Fleisch Pneumotachograph #2
8. Validyne DP-45 Transducer
9. Gould 2400 Strip Chart Recorder
10. O_2 source- LOX bottle (150 psi)
11. Multiplace Hyperbaric Chamber

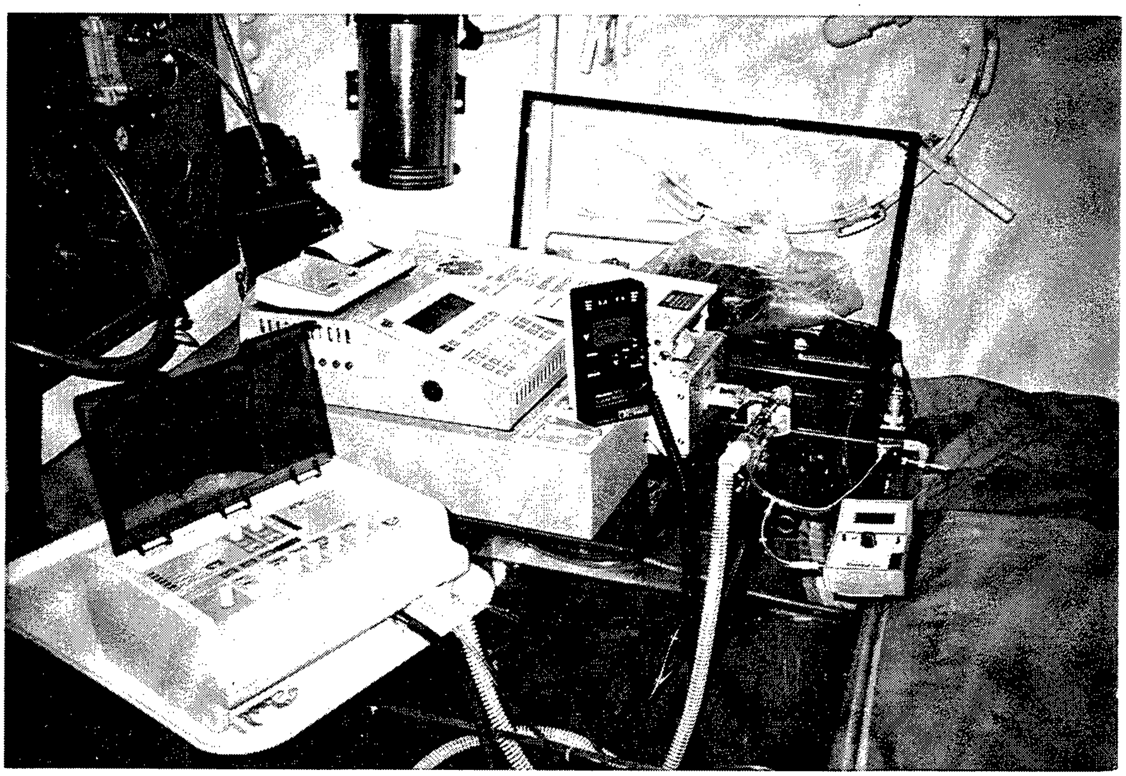


Figure 2. Test Setup

Test Procedures

The basic specifications of the BAV were verified at standard ambient conditions. Testing of this ventilator was divided into two phases.

Phase I. The BAV was exposed to an atmospheric pressure equivalent to 3 ATA (66 feet, sea water{fsw}or 29.4 psig) in the hyperbaric chamber. Once pressurized, operational checks were conducted on the membrane control switches to determine the effects increased atmospheric pressure had on structural integrity and operation of the unit.

Phase II. The BAV was performance tested in the control mode with the "required settings" (tidal volume, flow, and breath rate), set for a 1:2 inspiratory/expiratory ratio,(I:E). Assessment focused on the following clinical variables for safe, acceptable limits: (breath rate, tidal volume, flow rate, and proximal airway pressure.) Data was collected while the BAV was subjected to the following atmospheric pressures: 1 ATA, 2 ATA, 2.36 ATA, and 3 ATA, on lung compliances of .10 L/cm H2O and .05 L/cm H2O respectively**(5, 6).** Six samples were measured over a 10-minute period for upper and lower limits, tidal volumes of 2000 ml and 200 ml respectively. The first four samples were obtained over 2 min., at thirty second intervals. The final two samples were measured at 5 and 10 min. from the start of the test. Then in ascending order in increments of 200 ml, four samples were measured for tidal volumes of 400 ml to 1800 ml. As above, these samples were collected over 2 min., at thirty second intervals. The microprocessor component of the Bio-Tek VT-2 was used in the full test mode to obtain baseline values for rate, volume, pressure and flow. Due to its pressure sensitive diagnostic software, only the artificial lung simulator of the Bio-Tek VT-2 was used at atmospheric pressures greater than 1 ATA. The artificial lung simulator has a 2.2 liter capacity **(1)**. Performance checks were recorded at 1 ATA between testing at increased atmospheric pressures, to serve as BAV functional comparisons. Volume readings were measured with the Ohmeda 5410 volume monitor throughout the entire test procedure **(7)**. Flow was measured by the Fleisch Pneumotachograph #2. Proximal airway pressure readings were gathered by three devices:

1. BAV, Airway Pressure Transducer (LCD window atop the ventilator),
2. BioTek Universal Biometer DPM -III, and
3. Validyne DP-15.

Battery Performance Test

The 12VDC internal lead acid battery is rated for approximately 11 hrs. of operation and has a recharge time of 14-16 hrs. Continuous charging is permissible with the 12VDC power cable and the 115-220 VAC/60-400Hz multivoltage switch selectable power supply **(3)**.

With a full charge, the Bird Avian operated on battery power until the Battery Low/Fail Alarm activated. The unit was turned off and the battery was charged on 115VAC/60HZ power. After recharging for 24 hours, the unit was run on battery power until the Battery Low/Fail Alarm activated. Documentation was recorded on the battery charge and operation time.

RESULTS AND DISCUSSION

Phase I. The membrane-covered control switches were inoperable when exposed to 3 ATA, prohibiting the operator from adjusting settings. In order to proceed with testing, all membrane control switches were carefully vented with a #26 gauge needle to permit free venting across the membrane cover. Great care was taken in this process in order not to damage the internal circuitry. Structural integrity of the ventilator remained intact, and no aberrant functioning was observed with return to 1 ATA.

Phase II. In the control mode during volume cycled ventilation, the BAV provided acceptable tidal volumes in conjunction with proximal airway pressures and breath rates (within safe, acceptable limits). Initially there was some concern with the BAV's interpretation of the proximal airway pressure and peak inspiratory pressure. Values indicated by the unit were high and questions of their accuracy were raised. Two additional external airway pressure measurement devices were introduced, in parallel with the BAV pressure guage. Both devices were calibrated and unaffected by increased atmospheric pressure. These two items correlated within two integers of each other while the Bird Avian transducer continued to read at higher levels during testing. It was later discovered and reported to us by the Bird Corp. that the unusual readings were attributed to kinked tubing leading to the ventilator's airway pressure transducer. Measured tidal volume and flow were reduced to approximately 48% at 3 ATA, 40% at 2.36 ATA and 34% at 2 ATA of the set tidal volume and flow. The variance of measured tidal volumes between the two lung compliances tested was insignificant.

Thus, a conversion table (Appendix A) was developed to assist users in dialing the correct settings on the ventilator to obtain the desired or expected values at the corresponding atmospheric pressures. This conversion table was developed for each of the following clinical atmospheric pressures: 3 ATA, 2.36 ATA and 2 ATA, based on a 1:2 (I:E) ratio.

Battery Performance Test Results

The Bird Avian passed the battery performance test. The unit exceeding the manufacturer's guidelines of 11 hrs. and lasting 12 hrs. and 10 min., which was after full charge potential had been reached.

As mentioned, the Bird Avian battery is a self contained, hermetically sealed unit which appeared to pose little risk in the hyperbaric environment. After pressurization , the unit was observed for any obvious signs of battery electrolyte leakage or structural breakdown, and neither was evident.

Statistical Analysis

Measured tidal volumes (TV_m in ml) were recorded at three depths (ATA = 2.00, 2.36, and 3.00) and for ten of tidal volume settings (Tv_s= 200 to 2000 by 200 ml). There were also readings at ATA= 1.00 and TV_s = 2000ml. The model that seemed to fit the data most satisfactorily was of the form $TV_m = TV_s \times \{\alpha/(\alpha + ATA - 1)\}^{\beta}$. The nonlinear least squares program SAS NLIN, SAS Institute Cary, N.C. was used to obtain estimates of $\alpha = .880325$ and $\beta = .554740$. Tables for TV_s which produce desired values of TV_m, were then obtained by substituting in the TV_m's into the equation solving for the TV_s's. The associated estimates of flows were computed as 3 x (Rate) x TV, since I+E = 1+2 = 3. Statistical calculation and graphical representation of these data are depicted in Appendix B.

Limitations

The limitations of the Bird Avian portable ventilator when used in the hyperbaric environment are as follows: First, the unit has a gas leak of 1.5 - 3 L/min. This information was confirmed by the Bird Products Corp. engineers. In essence, this is the gas that is exiting the machine via the main and demand solenoid valves. When a breath is delivered, these valves are closed. However, between breaths, these valves open and the drive gas provided to the ventilator bleeds around these valves and exits the ventilator into the ambient chamber environment.

A second, related limitation involving excess gas emission is the patient exhalation valve. Our smaller multiplace chamber, in which the testing was conducted, has a volúme of 300 standard cubic feet and a circumference of 20.5 feet. Standard venting procedures were employed for this size chamber, therefore the increase in ambient chamber oxygen concentration did not pose a problem. However, a potential risk for high oxygen concentrations does exist with prolonged use or use in small multiplace hyperbaric chambers.

As mentioned previously, the breathing circuit on the Bird Avian ventilator (military version) has an anti-suffocation valve molded into the patient breathing circuit. This valve enables a patient to breathe ambient chamber air should the circuit shut down. We did not have the opportunity to evaluate the leak factor associated with this valve, which might indicate a patient receiving less than the 100% oxygen desired in the hyperbaric setting. For testing purposes, we simply obtained the commercial version of this valve and substituted it for the military version located in the breathing circuit.

The manufacturer of the lead acid battery does not recommend the battery be used under increased atmospheric pressures. No problems were observed with the battery during our tests of the BAV under pressure. The ventilator will operate off of 115-230 VAC electrical power. However, an explosion proof electrical outlet will be required.

Recommendations

The recommended drive gas pressure for the Bird Avian is between 40-60 psig. For the purpose of this study, we used 50 psig. To compensate for the ambient chamber pressure(g), while at depth, the drive gas pressure was increased proportionally. For example, the ambient chamber pressure at 3 ATA is 29.4 psig., therefore, the drive gas pressure should be increased from 50 psig. to 80 psig. This is addressed in the conversion tables. (Appendix A)

Also, it may be necessary to introduce an overboard dump mechanism adjacent to the exhalation valve on the breathing circuit to assist in keeping the chamber oxygen concentration at a safe level.

The manufacturer of the lead acid battery does not recommend the battery be used under increased atmospheric pressures. If operating ventilator on battery power, inspect for battery electrolyte leakage or breakdown in structural integrity.

REFERENCES

1. Bio-Tek Instruments, Inc. Ventilator Testers Models VT-1B & VT-2 Operator's Manual

2. Bird Products Corp. Operator Instructions & Maintenance Manual

3. Blake, Butch O. (1995). Test and Evaluation of the Bird Products, Corp. Bird Avian Portable Ventilator (Military Version) Model 15300 Brooks AFB, TX: Crew Technology Division, Armstrong Laboratory, Crew Systems Directorate.

4. Blanch, P. B., Desautels, D. A., & Gallagher, T. J., (1991) Deviations in Function of Mechanical Ventilators During Hyperbaric Compression. *Respiratory Care.*

5. Fried, Robert & Grimaldi, Joesph (1993). *The Psychology and Physiology of Breathing, In Behavioral Medicine, Clinical Psychology and Psychiatry.* New York: Plenum Press.

6. Knowles, John H. (1964). *Respiratory Physiology and It's Clinical Application.* Cambridge, Massachusetts: Harvard University Press

7. Youn, B. A., & Myers, Roy A. (1989). Volume Monitor for Mechanical Ventilation in the Hyperbaric Chamber. *Critical Care Medicine.*

ACKNOWLEDGEMENTS

I would like to thank all those who helped and advised during the evaluation of the Bird Products. Corp., Bird Avian portable ventilator [military version] Model 15300. I would especially like to thank, Maj. George Kemper, Larry P. Krock, Ph.D., Mr. Billy Jackson, Statistician , Ssgt. Rogelio Cano, Ssgt. David R. Case, and the entire staff from Aeromedical Testing and the Davis Hyperbaric Laboratory.

Appendix A

Davis Hyperbaric Laboratory Bird Avian Ventilator Conversion Table

DAVIS HYPERBARIC LABORATORY
BIRD AVIAN VENTILATOR
CONVERSION TABLE

	1 ATA		2 ATA		2.36 ATA		3 ATA	
RATE	**TVm**	**FLOWm**	**TVs**	**FLOWs**	**TVs**	**FLOWs**	**TVs**	**FLOWs**
6	200	3.6	305	5.5	336	6	386	6.9
6	400	7.2	609	11	672	12.1	772	13.9
6	600	10.8	914	16.5	1007	18.1	1158	20.8
6	800	14.4	1219	21.9	1343	24.2	1544	27.8
6	1000	18	1523	27.4	1679	30.2	1930	34.7
6	1200	21.6	1828	32.9	*	*	*	*
8	200	4.8	305	7.3	336	8.1	386	9.3
8	400	9.6	609	14.6	672	16.1	772	18.5
8	600	14.4	914	21.9	1007	24.2	1158	27.8
8	800	19.2	1219	29.3	1343	32.2	1544	37.1
8	1000	24	1523	36.6	1679	40.3	1930	46.3
8	1200	28.8	1828	43.9	*	*	*	*
10	200	6	305	9.1	336	10.1	386	11.6
10	400	12	609	18.3	672	20.1	772	23.2
10	600	18	914	27.4	1007	30.2	1158	34.7
10	800	24	1219	36.6	1343	40.3	1544	46.3
10	1000	30	1523	45.7	1679	50.4	1930	57.9
10	1200	36	1828	54.8	*	*	*	*
12	200	7.2	305	11	336	12.1	386	13.9
12	400	14.4	609	21.9	672	24.2	772	27.8
12	600	21.6	914	32.9	1007	36.3	1158	41.7
12	800	28.8	1219	43.9	1343	48.4	1544	55.6
12	1000	36	1523	54.8	1679	60.4	1930	69.5
12	1200	43.2	1828	65.8	*	*	*	*
14	200	8.4	305	12.8	336	14.1	386	16.2
14	400	16.8	609	25.6	672	28.2	772	32.4
14	600	25.2	914	38.4	1007	42.3	1158	48.6
14	800	33.6	1219	51.2	1343	56.4	1544	64.9
14	1000	42	1523	64	1679	70.5	1930	81.1
14	1200	50.4	1828	76.8	*	*	*	*
16	200	9.6	305	14.6	336	16.1	386	18.5
16	400	19.2	609	29.3	672	32.2	772	37.1
16	600	28.8	914	43.9	1007	48.4	1158	55.6
16	800	38.4	1219	58.5	1343	64.5	1544	74.1
16	1000	48	1523	73.1	1679	80.6	1930	92.6
16	1200	57.6	1828	87.8	*	*	*	*

TV = Tidal Volume
TVm = measured TV
FLOWm = measured FLOW
TVs = set TV
FLOWs = set FLOW

Volume Cycled Ventilation
with a 1:2 Inspiratory/Expiratory Ratio
* = TV not obtained

O_2 Drive Gas
2 ATA = 65psi
2.36 ATA = 70psi
3 ATA = 80psi

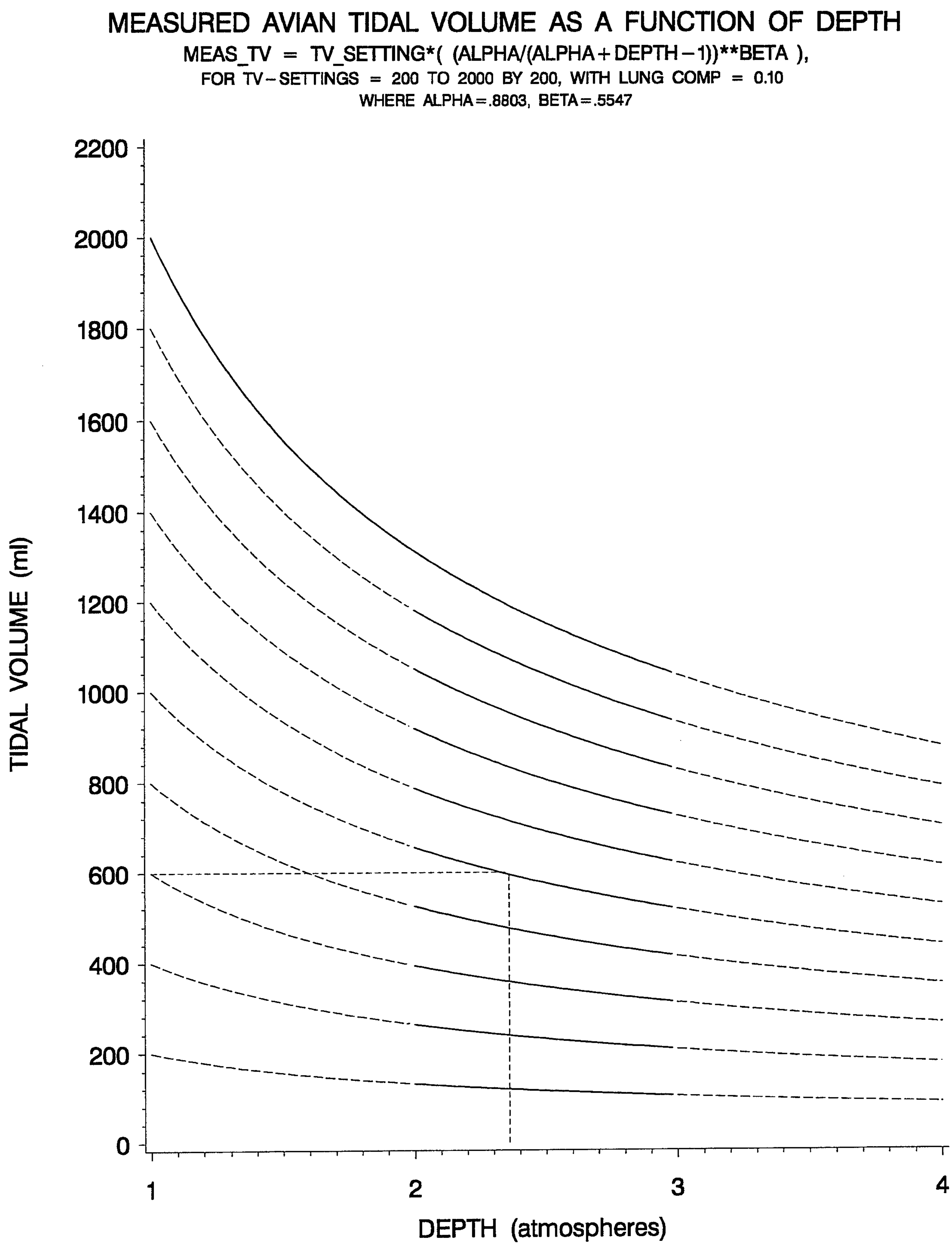
Appendix B

Effect of Hyperbaric Pressure on Avian Tidal Volume

The solid curves are within the range of the data; the dashed curves are extrapolations for the equation:

Measured TV = (TV setting at 1 ATA)x(.8803/(.8803+Depth-1))**.5547

The horizontal and vertical lines show how the numbers in the table in Appendix A can be obtained. To find the tidal volume setting at 1 ATA yielding a measured tidal volume of 600 ml at 2.36 ATA, go across from 600 on the y-axis and up from 2.36 on the x-axis and find the point of intersection. The curve, with the equation shown above, passes through the point of intersection, and follows that curve back to its y-intersect (in this case, about 1000 ml). Note in Appendix A to achieve a TV of 600 at 2.36 ATA, the recorded value of 1007 ml.



Lines are Constant Sea Level Tidal Volume Setting
(Solid lines are measured; dotted lines are calculated values)